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Gregory M. Fahy  
Application No.: 09/916,032  
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Atty. Dkt. No. 074066-0105  
(21CM1100-2)

**REMARKS**

By way of background, it is noted that preserved tissues can suffer from three distinct types of injury:

- 1) injury due to ice formation,
- 2) injury due to cryoprotectant toxicity, and
- 3) injury due to cooling itself, in the absence of ice formation.

Prior to the present invention, the prior art failed to address the third type of injury, i.e., injury due solely to the cooling of the sample. Instead, the prior art only provided methods for the prevention of ice nucleation and the prevention of cryoprotectant toxicity, neither of which is relevant to the invention as presently claimed. In contrast to the approaches taught in the prior art, the present invention provides crucial protection to tissues in a manner which was not available according to the teachings of the prior art.

Therefore, in accordance with the present invention, there are provided methods for minimizing or eliminating injury to a living system otherwise caused by cooling such living system without the formation of ice therein. Invention methods also facilitate the rapid introduction and washout of cryoprotectant fluids without toxicity or osmotic injury.

By the present communication, it is proposed that claims 19, 31, 35, 36 and 38 be amended, and new claim 46 added, to define Applicant's invention with greater particularity. For example, reference to "cooling injury" has been replaced throughout the claims with the phrase "injury . . . otherwise caused by cooling . . . without the formation of ice . . ." Thus, as amended, it is clear that the present claims are directed to the problem referred to in point (3) above, i.e., injury due to cooling itself, in the absence of ice formation. In contrast, all prior art applied in the Office Action is concerned exclusively with points (1) and (2) above. Consequently, the amendments submitted herewith render moot all previous rejections of record.

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No new matter has been introduced by the subject amendments as the amended claim language is fully supported by the specification and original claims. In addition, it is proposed to cancel claims 20, 29, 30, 33 and 37 without prejudice. Therefore, as a result of the proposed amendments, the number of claims presented for prosecution has been reduced. The proposed amendments submitted herewith are submitted to place the claims in condition for allowance, or, at a minimum, to reduce the issues for appeal. Accordingly, entry of the proposed amendments is submitted to be proper. Entry, therefore, is respectfully requested.

Upon entry of the proposed amendments submitted herewith, claims 19, 21-28, 31, 32, 34-36 and 34-46 will be pending in this application, with claims 19, 21-28, 31, 32, 34-37 and 46 under active prosecution. In view of the amendments submitted herewith, rejoinder of claims 38-45 is respectfully requested. A detailed listing of all claims that are, or were, in the application is presented herewith, beginning on page 2, along with an appropriate status identifier.

**Rejection in View U.S. Pat. No. 6,616,858 to Fahy**

The rejection of claims 19, 31-32 and 34-36 under 35 U.S.C. § 102(e), as allegedly being anticipated by U.S. Pat. No. 6,616,858 (hereinafter "the '858 Patent"), or in the alternative under 35 USC § 103(a) as allegedly being obvious in view of the '858 Patent, is respectfully traversed for at least the reasons of record. However, in order to reduce the issues and expedite prosecution, independent claims 19, 31 and 38, as amended herein (and new claim 46), incorporate the requirements of original claim 20, which is acknowledged to be free of the prior art (see the last 2 lines on page 10 of the Office Action).

Thus, the present invention, as defined, for example, by amended claim 19, distinguishes over the '858 Patent by providing a method for minimizing or eliminating injury to a living system otherwise caused by cooling the living system without the formation of ice therein. Invention method comprises administering to the living system a preservation medium having a tonicity which is sufficiently hypertonic to minimize injury caused by such cooling, wherein the

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preservation medium has a tonicity between 1 and 4 times isotonic, and wherein the preservation medium comprises a carrier solution and at least one cryoprotectant agent at a concentration sufficient to prevent freezing at a predetermined temperature below approximately 0°C, thereby minimizing or eliminating injury to the living system caused by such cooling. The '858 Patent does not disclose, describe or suggest such a method.

Independent claim 31 similarly distinguishes over the '858 Patent, and further requires that the preservation medium further comprise at least one polymer, in addition to a carrier solution and cryoprotective agent.

Independent (currently withdrawn, but subject to a request for rejoinder) claim 38 similarly distinguishes over the '858 Patent, and further requires that cooling of the living system be carried out in at least two separate cooling steps. Each of the steps contemplated by claim 38 is (similar to each of claims 19, 31 and 46) free of the prior art as they require the use of the same defined preservation medium for the same defined purpose as contemplated by claims 19, 31 and 46.

New claim 46 similarly distinguishes over the '858 Patent by providing a method for minimizing or eliminating injury to a living system otherwise caused by cooling the living system without the formation of ice therein.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(e), or in the alternative under 35 USC § 103(a) over the '858 Patent, are respectfully requested.

**Rejection Over Fahy (U.S. Pat. No. 6,616,858) in view of Fahy (U.S. Pat. No. 6,395,467)**

The rejection of claim 37 under 35 U.S.C. § 103(a) as allegedly being obvious over the '858 Patent, in view of U.S. Pat. No. 6,395,467 (hereinafter "the '467 Patent") is respectfully traversed for at least the reasons of record. This rejection has been rendered moot by the cancellation of claim 37.

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Claim 35, which has been amended to contemplate the optional presence of acetol, is not properly rejected over this combination of references. Claim 35 depends from amended claim 19, which, as discussed above, is free of the prior art. Claim 35, therefore, is also free of the prior art; additional reliance on the '467 Patent is unable to cure the acknowledged deficiencies of the '858 Patent.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) over the '858 Patent, in view of the '467 Patent are respectfully requested.

In view of the above amendments and remarks, it is respectfully submitted that the pending claims are in condition for allowance. Accordingly, reconsideration and favorable action on all claims are respectfully requested. In the event any issues remain in view of this communication, the Examiner is encouraged to contact the undersigned at the telephone number listed below so that a prompt disposition of this application can be achieved.

Respectfully submitted,

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